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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
[60Day-15-1019]  
Proposed Data Collections Submitted for  
Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

### **Proposed Project**

Integrating Community Pharmacists and Clinical Sites for Patient-Centered HIV Care (OMB No. 0920-1019, expires

05/31/2017) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).

### **Background and Brief Description**

Medication Therapy Management (MTM) is a group of pharmacist provided services that is independent of, but can occur in conjunction with, provision of medication. MTM encompasses a broad range of professional activities and cognitive services within the licensed pharmacists' scope of practice and can include monitoring prescription filling patterns and timing of refills, checking for medication interactions, patient education, and monitoring of patient response to drug therapy.

HIV specific MTM programs have demonstrated success in improving HIV medication therapy adherence and persistence. While MTM programs have been shown to be effective in increasing medication adherence for HIV-infected persons, no MTM programs have been expanded to incorporate primary medical providers in an effort to establish patient-centered HIV care. To address this problem CDC has entered into a public-private partnership with Walgreen Company (a.k.a Walgreens pharmacies, a national retail pharmacy chain) to develop and implement a model of HIV care that integrates community pharmacists with primary medical providers for patient-centered HIV care. The model program will

be implemented in ten sites and will provide patient-centered HIV care for approximately 1,000 persons.

The patient-centered HIV care model will include the core elements of MTM as well as additional services such as individualized medication adherence counseling, active monitoring of prescription refills and active collaboration between pharmacists and medical clinic providers to identify and resolve medication related treatment problems such as treatment effectiveness, adverse events and poor adherence. The expected outcomes of the model program are increased retention in HIV care, adherence to HIV medication therapy and viral load suppression.

On 16 May 2014, OMB approved the collection of standardized information from ten project sites over the three-year project period and one retrospective data collection during the first year of the three-year project period. The retrospective data collection will provide information about clients' baseline characteristics prior to participation in the model program which is needed to compare outcomes before and after program implementation. Minor formatting revisions are requested to the previously approved data collection forms. Lastly, CDC newly requests approval to conduct key informant interviews with program clinic and pharmacy staff in order to evaluate the program processes and to collect time and cost data which will

be used to estimate the cost of the model program. The key informant interviews and time and cost data are additional data collections from the original OMB approval.

Pharmacy, laboratory and medical data will be collected through abstraction of all participant clients' pharmacy and medical records. Pharmacy, laboratory and medical data are needed to monitor retention in care, adherence to therapy, viral load suppression and other health outcomes. Program specific data, such as the number of MTM elements completed per project site and time spent on program activities, will be collected by program. Qualitative data will be gathered from program staff through in-person or telephone interviews.

The data collection will allow CDC to conduct continuous program performance monitoring which includes identification of barriers to program implementation, solutions to those barriers, and documentation of client health outcomes. Performance monitoring will allow the model program to be adjusted, as needed, in order to develop a final implementation model that is self-sustaining and which can be used to establish similar collaborations in a variety of clinical settings. Collection of cost data will allow for the cost of the program to be estimated.

There is no cost to participants other than their time.

Estimated Annualized Burden Hours

Type of respondent	Form Name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Clinic Data Manager	Project clinic characteristics form	10	3	30/60	15
Pharmacist	Project pharmacy characteristics form	10	3	30/60	15
Clinic Data Manager	Patient Demographic Information form	10	100	5/60	83
Clinic Data Manager	Initial patient information form	10	100	1	1,000
Clinic Data Manager	Quarterly patient information form	10	400	30/60	2,000
Pharmacist	Pharmacy record abstraction form	10	400	30/60	2,000
Key informants	Interviewer data collection worksheet	60	2	30/60	60
Clinic staff	Clinic cost form	20	2	10	400
Pharmacy staff	Pharmacy cost form	20	2	10	400
Total					5,973

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